



# FDA and the Challenge of Alternative Medicine: Realistic Assessments and Regulatory Flexibility

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## I. Introduction

For many people in the United States the idea of alternative or unconventional medicine conjures up visions of snake oil salesmen or crazy crystal-bearing shamen. Such images contribute to the gut reaction that alternative medicine is bunk. Recently, however, Americans have taken increasingly active roles in their own health care and, in the process, have discovered the potentials of alternative medicine. This growing fascination with alternative medicine is evidenced by the recent deluge of books, magazines, web sites, health stores, and clinics dedicated to its practice and development.

The perception that alternative medicine cannot be reconciled with conventional medicine and science belies both the enchantment with unconventional therapies as well as the distrust of them. In 1993 Congress, however, decided that America *should* take a more scientific look at alternative medicine and established within the Office of the Director of the National Institutes of Health (NIH) the Office of Alternative Medicine (OAM). The function of the OAM is to facilitate the evaluation of alternative medical treatment modalities, including acupuncture and Oriental medicine, homeopathic medicine, and physical manipulation therapies.<sup>1</sup> Congress's establishment of this office signals a recognition of alternative medicine as more than mere quackery and as a potential source of legitimate health care for many Americans.

Because the Food and Drug Administration (FDA) is the regulatory body with the most powerful influence over the health of the American population, how the Agency addresses alternative medicine will be central to developing the role that it plays in American health care. So far, however, FDA has not demonstrated foresight in this area. Through its actions, inactions, official statements, and propaganda, FDA has displayed

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<sup>1</sup>42 U.S.C.A. §283g (1997).

a simple lack of coherent policy toward alternative medicine. Part of FDA's failure to develop meaningful policy on alternative medicine stems from its failure to consider alternative medicine in a realistic way. As a result, FDA has been ineffective in contributing to the goal that alternative medicine be a safe and viable health care option for Americans. Section II sets forth the proposition that alternative medicine demands serious and immediate attention from FDA. Section III provides a discussion of the ways in which FDA has failed think about alternative medicine in a realistic way and the reasons why its current regulatory framework is unworkable for alternative medicine. Section IV presents FDA's inchoate policies toward alternative medicine and examines their impact on the development of alternative medicine in American health care. Section V proposes that FDA create flexibility within its conventional regulatory scheme to facilitate the goal of making alternative medicine a safe viable health care choice in the U.S.

## II. Why FDA Must Seriously Address Alternative Medicine.

With pressing concerns like cancer, AIDS, breast implants, and bovine growth hormones to attend to, why should FDA commit time and resources to addressing alternative medicine, a seemingly fringe activity with limited threats to public safety? The answer is two-fold. First, a significant portion of the American population uses alternative medicine. Obviously, the more widespread the use of unconventional therapies, the more widespread the effects, whether beneficial or harmful. Second, unconventional medicine has the potential to contribute to health care cost containment.

### A. *Alternative Medicine Has a Major Presence in the United States.*

Although alternative medicine may appear to be on the fringes of health care, recent evidence indicates that it plays a role in the lives of a significant portion of the American population. In a widely cited study published in the *New England Journal of Medicine*, researchers determined that the frequency of use of alternative medicine in the United States was significantly greater than previously believed<sup>2</sup>. In 1990 approximately 34% of Americans used at least one unconventional therapy<sup>3</sup>. Of these individuals approximately one-third visited alternative health care providers for that therapy<sup>4</sup>. These visits to alternative health care providers totalled 425 million, which is noticeably greater than the 388 million visits to all U.S. primary care physicians<sup>5</sup>. Expenditures on alternative therapies totalled \$13.7 billion, 75% of which was paid out of pocket (\$10.3 billion)<sup>6</sup>. These out-of-pocket payments can hardly be considered insignificant when compared with the \$12.8 billion spent out of pocket annually for all hospitalizations in the U.S.<sup>7</sup>

This study also found that the highest use of unconventional medicine was by non-black persons between the ages of twenty-five and forty-nine with relatively more education and higher incomes.<sup>8</sup> The unconventional medicines were most commonly used for chronic, non-life-threatening, medical conditions.<sup>9</sup> Eighty-three percent of the people who used alternative therapies also sought treatment from a medical doctor.<sup>10</sup> Seventy-three percent, however, did not tell their medical doctors that they were using unconventional therapies, creating obvious drug interaction concerns.<sup>11</sup>

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<sup>2</sup>David M. Eisenberg et al., *Unconventional Medicine in the United States—Prevalence, Costs, And Patterns of Use (Special Article)*, THE NEW ENGLAND JOURNAL OF MEDICINE, January 28, 1993, at 246-252.

<sup>3</sup>This study defined unconventional therapies as: [M]edical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals. Examples include acupuncture, chiropractic, and massage therapy. *Id.*

<sup>4</sup>*Id.*

<sup>5</sup>*Id.*

<sup>6</sup>*Id.*

<sup>7</sup>*Id.*

<sup>8</sup>*Id.*

<sup>9</sup>*Id.*

<sup>10</sup>*Id.*

<sup>11</sup>*Id.*

Alternative medicine, with both its benefits and risks, has clearly established itself in the lives and bodies of many Americans. As the major regulatory force in this area, FDA has a responsibility to recognize and consider its role in the development of unconventional therapies. Specifically, FDA must handle alternative medicine in a way that will maximize the benefits to users, while minimizing the safety risks.

*B. Alternative Medicine as an Ingredient of Health Care Reform.*

As the search for a solution to the health care crisis in America continues, alternative medicine has been touted as one way to alleviate some of the high costs of health care. Part of Congress's motivation in passing the Dietary Supplement Health and Education Act of 1994 (DSHEA)<sup>12</sup>, was the potential benefit of alternative medicine to the health of Americans. A stated purpose of the Act is to improve the health status of the people of the United States and help constrain runaway health care spending by ensuring that the Federal Government erects no barriers that impede the ability of consumers to improve their nutrition through the free choice of safe dietary supplements.<sup>13</sup>

Because FDA's control over dietary supplements prior to the act threatened their availability for use, passage of DSHEA was considered an important victory for supporters of alternative medicine, which relies heavily on many of the products that fall under the Act. As explained in the Senate Committee Report, DSHEA was prompted by findings that, [T]he importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies; there is a definitive link between the ingestion of certain nutrients or dietary supplements and the prevention of disease; and healthful diets may mitigate the need for expensive medical procedures.<sup>14</sup> Specifically, the

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<sup>12</sup>Dietary Supplement Health and Education Act of 1994, 103 P.L. 417, 108 Stat. 4325 (1994).

<sup>13</sup>*Id.*

<sup>14</sup>Senate Committee on Labor and Human Resources, Dietary Supplement Health and Education Act of 1994, S. Rep. No.

Committee Report found, [P]reventive health measures, including education, good nutrition and appropriate use of safe dietary supplements will limit the incidence of chronic diseases and reduce long-term health care expenditures; and that reduction in health care expenditures is of paramount importance to the future of the country and its economic well-being, since the country will spend over one trillion dollars on health care in 1994.<sup>15</sup>

Alternative medicine and dietary supplements, in particular, may assist in health care cost containment in two ways: disease prevention and self-care<sup>16</sup>. As Robert S. McCaleb of the Herb Research Foundation testified:

Opinions differ about the [preventive] value of supplements, and it may take years to sort out 'the truth'. In the meantime, supplements must be sold without disclosing what is already known about their effects... Millions of [Americans] are willing to spend their own resources on protecting their health through diet, exercise and supplements. They are not charging their herbs and vitamins to insurance companies or Medicaid. They are taking personal responsibility for their health care and attempting to practice preventive medicine, just as they should. Under the current [pre-DSHEA] regulatory system, this can be hard to do.<sup>17</sup>

Because herbal medicines and other forms of alternative medicine have significant potential to help reduce health care costs, as Congress has recognized, FDA must take into serious consideration how its activities will promote or discourage realization of that potential.

### III. FDA's Unrealistic View of Alternative Medicine and the Regulatory Implications

#### A. What Is Alternative Medicine?

410, 103d Cong., 2d Sess. (1994) [hereinafter DSHEA Report].

<sup>15</sup>*Id.*

<sup>16</sup>*Rational Regulation of Herbal Products: Testimony Before the Subcomm. on Health and the Environment of the House Comm. on Energy, Health and the Environment*, 102d Cong. (July 29, 1993)(testimony of Robert S. McCaleb, Herb Research Foundation).

Alternative medicine is sometimes described as any medical practice or intervention that: \*lacks sufficient documentation of its safety and effectiveness against specific diseases and conditions \* is not generally taught in U.S. medical schools \* is not generally reimbursable by health insurance providers.<sup>18</sup> While the broadness of this definition is understandable, it is important to *remember* that such a definition encompasses an expansive spectrum of practices, from traditional Chinese medicine to biofeedback to ozone generators to crystal healing. For purposes of regulatory analysis, I will divide this broad definition of alternative medicine into the following categories: (1) systems of medicine, (2) specific therapies that are unapproved, but not related to Category (1), (3) relatively harmless practices, and (4) phony alternative medicines. These categories will help to clarify the relevant issues surrounding alternative medicine.

Included in Category (1) are the mostly self-sufficient bodies of medicine that are alternative in the sense they are premised on philosophies that are different from those of conventional American medicine. This is the most promising category of alternative medicine because it covers systems of care that are the conventional medicines of other cultures or widely practiced by certain segments of the U.S. population. As Senate Minority Leader Tom Daschle, an important proponent of alternative medicine, pointed out, Between 70 and 90 percent of the health care practiced in this world is considered 'alternative' by FDA standards.... In fact, many of the treatments now recognized as 'conventional' by FDA were once considered 'alternative.'<sup>19</sup> This statement correctly recognizes the cultural biases inherent in perceptions of acceptable versus unacceptable forms of medicine.

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<sup>18</sup>Isadora B. Stehlin, *An FDA Guide to Choosing Medical Treatment*, FDA CONSUMER, June 1995, at 10 [hereinafter *Guide*].

<sup>19</sup>*Medical Treatment: Testimony Before the Senate Labor & Human Resources Comm.*, 105th Cong. (July 30, 1996)(testimony by Senate Democratic Leader Tom Daschle).

Among the most accepted bodies of medicine in this category in the U.S. are osteopathic manipulative therapy (OMT)<sup>20</sup>, homeopathy<sup>21</sup> and chiropractic<sup>22</sup>. Although the reputation of these medicines is lightly tainted by visions of quackery, they represent the major systems of alternative care in the U.S.

Hardly considered alternative in other cultures, traditional Chinese medicine (TCM)<sup>23</sup> and Ayurveda<sup>24</sup> (traditional Indian medicine) also belong in this category. Both TCM and Ayurveda rely on a vast herbal pharmacopoeia.<sup>25</sup> Related to these medicines is the more general practice of herbal medicine, which uses a variety of herbs in various forms to prevent and treat a wide range of diseases. The medicines that should fall into Category (1) tend to be both preventive and curative in nature, but also view health in a more holistic, integrated way. As a result the line between medicine and lifestyle grows rather tenuous.

Category (2) alternative medicines include very specific therapies that are not yet (or will never be) approved by FDA. Many of these are drugs or devices that are just too new to be approved. Some will pass through

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<sup>20</sup>OMT is based on the principle of manipulating the body mechanically to allow the circulatory and nervous systems to bring natural healing powers to ailing parts of the body. Most osteopaths today, however, do not use manipulation as the primary method of treatment; instead they rely on the same drugs and surgery used by medical doctors. Andrew Weil, SPONTANEOUS HEALING 29 (Alford A. Knopf 1995).

<sup>21</sup>Established 200 years ago, homeopathic medicine is based on the theory that like treats like. Because the remedies are so highly diluted, they pose insignificant threats to safety. The dilutions are supposed to work on the body's energy field, catalyzing natural healing responses, but critics maintain that they are purely placebos. *Id.* at 244.

<sup>22</sup>Chiropractic, which uses spinal adjustment to cure ailments, was established a century ago and has had a history of being attacked as quackery. In 1971 the American Medical Association's Committee on Quackery declared as its 'primary mission'... 'first, the containment of chiropractic, and, ultimately, the elimination of chiropractic.' As chiropractors have become more scientifically trained, however, they have gained increasing mainstream acceptance. James S. Gordon, MANIFESTO FOR A NEW MEDICINE 172 (Addison-Wesley 1996).

<sup>23</sup>Diagnosis in TCM is based on history, on observation of the body (especially the tongue), on palpitation, and on pulse diagnosis, an elaborate procedure requiring considerable skill and experience. Treatment involves dietary change, massage, medicinal teas and other preparations made primarily from herbs but also including animal ingredients, and acupuncture. The Chinese herbal pharmacopoeia is vast, with many plants now under serious scrutiny by Western pharmacologists. Weil, *supra* note 20, at 242.

<sup>24</sup>Ayurveda is one of the oldest systems of medicine, but has only recently become widely available in the West. Practitioners diagnose by observing patients, questioning them, touching them, and taking pulses. With this information the practitioner is able to assign patients to one of three major constitutional types and then to various subtypes. This classification dictates dietary modifications and selection of remedies. Ayurvedic remedies are primarily herbal, drawing on the vast botanical wealth of the Indian subcontinent, but may include animal and mineral ingredients, even powdered gemstones. Other treatments include steam baths and oil massages. Weil, *supra* note 20, at 239.

<sup>25</sup>Weil, *supra* note 20, at 239, 242.



the proper regulatory channels and become conventional, others will appropriately be discarded. Found in the shadier parts of this category are unapproved practices such as ozone therapy. This controversial therapy utilizes an ozone generator, which creates a toxic form of oxygen to kill fungal and viral infections. Originally presented as an alternative and less invasive cancer therapy<sup>26</sup> and more recently touted as a potential treatment for AIDS<sup>27</sup>, ozone therapy is generally considered dangerous. According to FDA, [T]he machine is unapproved, dangerous and has caused at least three deaths... when patients received extreme doses.<sup>28</sup>

Category (3) contains alternative practices that are relatively harmless, but are probably the hardest to examine scientifically because they tend to be more spiritual in nature. Some examples include religious healing, crystal healing and guided imagery therapy. These types of medicines probably present few or no safety concerns, but are also the least promising in terms of potential benefit on a large scale.

Category (4) is not really alternative medicine, but phony alternative medicine and includes the malpractice or abuse of it. The particular concern with these types of products is that they often profess to be natural and therefore safe, but are consumed in such concentrated doses that they are toxic and even deadly. This category of phony alternative medicine casts doubt upon the real medicines of Category (1). Basic health fraud could also be included in this category.

While FDA or anyone else could certainly devise a different taxonomy for alternative medicine, the point is that *some* division must be made. Without any categorization, discussion of FDA policy toward alternative medicine is nonsensical, for it would clearly be ridiculous to treat TCM, with its two-thousand year old history, in the same manner as a newfangled device like an ozone generator. A realistic view of alternative

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<sup>26</sup>Michael H. Cohen, *Holistic Health Care: Including Alternative and Complementary Medicine in Insurance and Regulatory Schemes*, 38 ARIZ. L. REV. 83, 119 (1996).

<sup>27</sup>Danny Westneat, *Armed with Vitamins, And Now a Gun—FDA Foe Becomes Folk Hero*, THE SEATTLE TIMES, July 4, 1995, at A1.

<sup>28</sup>*Id.*

medicine includes a recognition of the expansiveness of the alternative medicine and its difficulties, as well as an attempt to create meaningful subdivisions for policy analysis.

*B. Alternative Medicine Is Not Health Fraud.*

There is an obvious reason why images of alternative medicine get tangled up in images of quackery: Since both promote unapproved therapies, how are the good to be separated from the bad? While it may be difficult to distinguish Category (4) products from Category (1) products, FDA must put forth the effort. If FDA takes a realistic look at health fraud and alternative medicine, it might find that the intersection of the two are not so large. According to FDA, teenagers and the elderly are the chief targets for health fraud promoters.<sup>29</sup> According to the *New England Journal of Medicine* study<sup>30</sup>, however, it is mostly individuals between the ages of twenty-five and forty-nine with relatively higher levels of income and education who are using alternative medicine. The people using alternative medicine in America are mostly those who will spend the time and resources to learn more about their health so that they may take a more active role in improving it. While FDA will always need to crack down on health fraud, it needs to separate that issue from alternative medicine.

*C. FDA's False Self-Conception of Being Encouraging Toward the Development of Alternative Medicine*

FDA cites as evidence of its open-mindedness, flexibility and ability to adapt to the challenge of alterna-

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<sup>29</sup> *Guide*, *supra* note 19.

<sup>30</sup> Eisenberg, *supra* note 2.

tive medicine the IND (investigational new drug) process and the IDE (investigational device exemption) process<sup>31</sup>. In Senate testimony on access to medical care, Jerrold Mande, Executive Assistant to the Commissioner of Food and Drugs, explained, FDA's flexibility and open-mindedness in seeking new ways to help patients are [demonstrated by] the INDs for thalidomide—a product with a well-known history. While thalidomide is hazardous when used during pregnancy, it may be helpful for a variety of different indications. Despite the initial absence of a sponsoring company, FDA worked with individual investigators to make promising strides in the safe use of thalidomide to treat severe canker sores in AIDS patients [and several other hopeless diseases].<sup>32</sup> While opening access to various untested remedies for life-threatening diseases when nothing else will work is certainly a good idea, particularly for Category (2) therapies, its usefulness for the development of alternative medicines in Category (1) is slim.

Mande also boasts as evidence of FDA being instrumental in addressing the new and varied challenges posed by alternative and complementary products the reclassification of acupuncture needles from a Class III to a Class II medical device<sup>33</sup>. While FDA is certainly moving in the right direction, one cannot help questioning why that step has taken so long in light of the device's history of use that is many times longer than the history of the United States. Mande also cites as evidence of FDA's instrumentality the fact that most botanical products are legally marketed as dietary supplements without any impediments by FDA. To credit itself for not interfering with most botanicals, however, is either unrealistic or downright dishonest. As discussed in Section II, DSHEA was passed for the very purpose of removing from FDA the control it did not want to surrender.<sup>34</sup>

#### *D. The Current Regulatory Climate Is Inadequate for Many Types of Alternative Medicines.*

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<sup>31</sup>*Medical Treatment: Testimony Before the Sen. Comm. on Labor and Human Resources*, 105th Cong. (1996)(testimony of Jerrold Mande, Executive Assistant to the Commissioner of Food and Drugs).

<sup>32</sup>*Id.*

<sup>33</sup>*Id.*

<sup>34</sup>FDA is however, in the process of developing a guidance document on botanicals. Mande, *supra* note 32.

Because Category (1) alternative medicines are premised on philosophies that differ from conventional American medicine, they cannot develop within the conventional regulatory framework. FDA presents itself as open-minded and even-handed toward alternative medicine in that it wants patients to have early access to novel medical interventions, regardless of whether they are conventional, 'alternative,' or 'complementary.'

<sup>35</sup> From the perspective of FDA, [I]t doesn't matter whether the product or treatment is labeled alternative or falls under the auspices of mainstream American medical practice... It must meet the agency's safety and effectiveness criteria before being allowed on the market.<sup>36</sup> The problem with this so-called unbiased approach to alternative medicine is that it fails to acknowledge the fact that many are based on philosophies of medicine that are fundamentally different from the disease treatment philosophy of conventional medicine. For instance, several alternative medicines follow the premise that a person's body has natural healing powers and emphasis should be placed on prevention through enhancing these powers.<sup>37</sup> Amidst the backdrop of conventional medicine, however, FDA's regulatory framework has developed as a system eager for curative, rather than preventive therapies. For example, Robert McCaleb points to the dearth of preventive medicine as evidence of this in tandem development:

The American health care system has been characterized as a 'disease treatment system' because of the conspicuous absence of approved preventive medicines... Preventive medicine, frequently touted as a key to lowering health care costs is thwarted by FDA's current regulatory policies... In the U.S. we have no legitimate place in our regulatory framework for preventive medicines. After over 50 years of drug regulation, the FDA has not approved a single over-the-counter drug for internal use in the prevention of any major disease. The only non-prescription preventive medicines approved by FDA are fluoride toothpaste, sunscreen and motion sickness pills. During the 20 year process of 'reviewing' OTC ingredients, FDA never even established a category in which preventive medicine products could be considered. We have a few prescription preventive

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<sup>35</sup> *Id.*

<sup>36</sup> *Guide*, *supra* note 19.

<sup>37</sup> *See* Weil, *supra* note 21.

drugs, such as those to treat hypertension and lower blood cholesterol, but these are available only to those with a pathological condition. Our only other preventive medicines, like vaccines and antimalarials, are also prescription only....<sup>3839</sup>

Another example of how FDA fails to recognize alternative medicine's alternative basic principles is its attitude toward clinical trials. In an *FDA Consumer* article, FDA recommends that anyone wishing to explore alternative therapies should participate in one of the currently ongoing clinical trials, including studies of: acupuncture to treat depression, attention-deficit hyperactivity disorder, osteoarthritis, and various pains; Ayurvedic herbals for Parkinson's disease; biofeedback for diabetes and various pains; electric currents for tumors; and imagery therapy for asthma and cancer.<sup>40</sup> This seemingly harmless recommendation illustrates several points. First, none of these trials were designed to examine the preventive aspects of alternative care, which demonstrates a blatant dismissal of perhaps the most important part of alternative medicine. Second, the testing of preventive therapies for curative properties sets up them for failure, which will cast doubt upon their usefulness for more preventive purposes. Third, using the conventional paradigm of trying to isolate specific treatments for specific indications disregards the holistic, integrative and patient-specific nature of many forms of alternative medicine.

Even when the philosophical differences are placed aside, there are logistical problems in obtaining the kind of scientific evidence required for conventional medicines. Acupuncture provides a good example. To test the efficacy of a therapy, researchers use patients with all the same medical diagnosis.<sup>41</sup> This conventional method might not work for acupuncture, which offers treatment based on all facets of an individual, rather than just the symptoms of disease.<sup>42</sup> The placebo-controlled, double-blind study design of Western research

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<sup>38</sup>McCaleb, *supra* note 17.

<sup>39</sup>Recently, FDA approved another preventive OTC drug, bentoquatam, which protects against poison ivy. See Ivy Fleischer Kupec, *FDA Approves First Drug That Protects Against Poison Ivy*, FDA Answers, Aug. 28, 1996. See <http://www.fda.gov/bbs/topics/ANSWERS/ANS00757>.

<sup>41</sup>*Acupuncture (Can This Ancient Treatment Help to Control Problems Like Pain and Addiction?)*, CONSUMER REPORTS, January 1994 at 54-59.

<sup>42</sup>*Id.*

causes problems for the testing of acupuncture.<sup>43</sup> In a double-blind study, neither the subject nor the investigator knows which individuals are receiving treatment.<sup>44</sup> Because an acupuncturist must know where, at what angle and with what motion to insert the needles, designing a double blind study would be impossible.<sup>45</sup> The inevitable result is a long history of successful use, but limited scientific evidence of efficacy to satisfy conventional standards.

Homeopathy is an important example of alternative medicine not fitting into the conventional regulatory paradigm because it is the one area where FDA did recognize the incompatibility and correctly responded. This section will only mention the difficulties of making homeopathy function within the conventional regulatory system; Section IV.A.4 will detail FDA's regulatory responsiveness to the dilemma. Homeopathy is based on German physician Samuel Hahnemann's law of similars. Under this theory of medicine, extremely small doses of substances that would cause symptoms similar to those of the disease in a healthy person actually cure an ailing person of the disease. According to Dana Ullman, President of the Foundation for Homeopathic Education and Research and spokesperson for the National Center for Homeopathy, homeopathic products have to be treated differently from conventional products, 'Like acupuncture, homeopathy is a different system of treating people... It doesn't treat diseases per se, but treats people who are ill. Doing research on these methods requires a different type of research design.'<sup>46</sup>

Because alternative medicines are so different in philosophy from conventional medicine, the conventional regulatory climate is inappropriate for them. FDA must shift its mind-set to recognize these differences before it can meaningfully and realistically address the difficulties of alternative medicine.

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<sup>43</sup>*Id.*

<sup>44</sup>*Id.*

<sup>45</sup>*Id.*

<sup>46</sup>Andrew A. Skolnick, *FDA Petitioned To 'Stop Homeopathy Scam'*, 272 THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1154 (1994).

#### IV. FDA's Inchoate Policies on Alternative Medicine and Their Impact

As explained in Section III, FDA's reluctance to accept the reality that to the extent that alternative medicines are premised on alternative philosophies, applying the conventional regulatory framework is simply inappropriate. By not making some paradigmatic shift, FDA has been confined to trying to force alternative medicine into the conventional regulatory system or just to disregarding it. This kind of unthinking action and inaction demonstrates a failure to meet the challenges of alternative medicines, and sends confusing signals to the public about the safety and desirability of alternative medicine.

##### *A. FDA's Inconsistency on Alternative Medicine.*

###### *1. A Control-Freakish FDA.*

FDA's relentless efforts to preserve supreme control over vitamins and other dietary supplements reveal the control-freak side of the Agency and indicate an aversion toward alternative medicine based mostly on an unwillingness to lose any regulatory control, rather than something more substantive. The history behind the passage of DSHEA is a clear illustration of FDA's insistence on maintaining control over vitamins and other dietary supplements with blatant disregard for public sentiment, Congress, and the courts.

The Committee Report on DSHEA details this history well<sup>47</sup>: In the decades preceding DSHEA, FDA had developed an increasingly aggressive approach toward regulating supplements. In 1962 FDA issued regu-

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<sup>47</sup>DSHEA Report, *supra* note 14.

lations setting minimum and maximum levels for supplements, but eventually withdrew them in the face of strong citizen protest. Between 1966 and 1973 FDA attempted to classify vitamins as over-the counter (OTC) drugs if the product surpassed 150% of the Recommended Daily Allowance (RDA). Congress blocked FDA with the Proxmire/Rogers amendment to the FD&C Act. Refusing to take the cue from Congress, FDA attempted to regulate vitamins in the late 1970s on the basis that because they were toxic, their potencies could be regulated. The FDA's attempt to get around the Amendment, however, was rebuffed by the federal courts. Still determined to assert control over vitamins, in 1980 FDA issued a proposed OTC drug monograph for vitamins and minerals which purported to deal only with potencies above the RDA, but implicitly imposed potency limits. Only after strong public opposition did FDA withdraw the proposal. Continuing its obsession with controlling vitamins, FDA formulated a 'food additive theory' to ban the sale of supplements that made no health claims: Essentially, the theory was that any ingredient added to a capsule or tablet rendered the resulting dietary supplement a food additive because the ingredient was added to the capsule or tablet. Under this theory, FDA could not lose, as it needed only to furnish an affidavit from one of its scientists stating that experts generally did not regard the product as safe. The actual safety of the product was never at issue.<sup>48</sup> FDA's creative construction of the law to prevent marketing of dietary supplements was denounced by the federal courts. In two 1993 cases<sup>49</sup> FDA argued that the black currant oil in capsules of black currant oil constituted a food additive to the capsule and was of questionable safety. In both cases the courts held that the black currant oil could not be considered a food additive, so the manufacturer did not have the burden of proving that the oil was generally regarded as safe (GRAS). In *Two Plastic Drums*, the court expounded upon the ridiculousness of FDA's position, which taken to the extreme would classify every component of food as a food additive, and chided, The only justification for

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<sup>48</sup>DSHEA Report.

<sup>49</sup>See U.S. v. Two Plastic Drums... Black Currant Oil..., 984 F.2d 814 (7th Cir. 1993) and U.S. v. Twenty-nine Cartons of \* \* \* An Article of Food, Etc., 987 F.2d 33 (1st Cir. 1993).



this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors then burden of proving the safety of a substance in all circumstances.<sup>50</sup>

Congress finally put an end to FDA's control with the passage of DSHEA. The Act is the most recent and probably the most important attempt to check FDA authority in the area of alternative medicine because the vitamins and herbs used in many forms of alternative medicine are considered dietary supplements under the Act.<sup>51</sup> DSHEA, which was specifically proposed to stop FDA from removing many herbs and other supplements from the market or regulating them as drugs, elicited the greatest amount of constituent response of any bill in history of Congress.<sup>52</sup>

This history depicts FDA's opposition to alternative medicine as a by-product of its desire to retain as much control as possible.

## *2. A Tough Cop FDA.*

A widely publicized FDA raid in 1992 revealed a tough cop side to FDA and led many people to believe that the agency was on a crusade to stomp out alternative medicine. In the high Kent, Washington raid, more than two dozen federal and state law enforcement officers, including FDA agents, stormed an alternative medicine clinic and pharmacy in the same shopping plaza. The clinic was run by Dr. Jonathan Wright, who, with a college degree from Harvard and a medical degree from the University of Michigan, does not fit the stereotype of a medical quack. After eight months of sifting through the clinic's garbage cans, FDA officers,

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<sup>50</sup>*Two Plastic Drums*, 984 F.2d 814 at 819.

<sup>51</sup>21 U.S.C.A. §321(ff) (1997).

<sup>52</sup>*Alternative Medicine Offers Answers for Health Reform*, BIOTECH FINANCIAL REPORTS, May 1995.

accompanied by armed police officers in flak jackets, seized \$100,000 worth of medicines and equipment.<sup>53</sup> Some of the items seized included injectable vitamins, minerals, glandular extracts, photocopies of patient records, and devices that measure the electromagnetic energy of the body to test people for allergies.<sup>54</sup> The raid created an world-wide blaze of negative publicity for FDA. More than two thousand letters were faxed to the White House within 24 hours sharply criticizing the FDA action. Newspapers were filled with articles denouncing the SWAT-like team of U.S. Food and Drug Administration agents... [who] effectively terrorized the staff and patients.<sup>55</sup> In a testimony on Regulatory Flexibility Proposals in 1995, this incident was even used as an example of the general need to increase checks on regulatory powers<sup>56</sup>. According to that testimony, FDA public affairs officials explained that they had 'to play a little rough to send a message to the whole industry.'<sup>57</sup> FDA Commissioner David Kessler defended, 'The search uncovered the illegal and dangerous products that the FDA and sheriffs believed were present at the clinic.'<sup>58</sup>

### 3. *An Indifferent FDA.*

In sharp contrast to FDA's super-cop enforcement tactics, a quick browse through a health food store or Chinatown will reveal an FDA with little interest in enforcement. Health food stores are rife with products that are either labelled with specific health claims or sold in juxtaposition to publications detailing such health benefits. Similarly, stores in Chinatown regularly sell TCM herbal products, with labelling ranging from general statements of improving energy to bold claims of curing diseases such as AIDS. The FD&C Act

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<sup>53</sup>Westneat, *supra* note 27.

<sup>54</sup>*Id.*

<sup>55</sup>*Questionable Tactics-Motives Suspect in Health Store Raids (Editorial)*, THE FORT WORTH STAR-TELEGRAM, August 21, 1992.

<sup>56</sup>*Regulatory Flexibility Proposals: Testimony Before the House Judiciary Subcomm. on commercial and Administrative Law of the House Comm. on the Judiciary*, 104th Cong. (February 3, 1995)(testimony of Susan Eckerly, Deputy Director of Economic Policy and Walker senior fellow in economic policy at The Heritage Foundation.)

<sup>57</sup>*Id.*

<sup>58</sup>*Id.*

prohibits dietary supplement statements that claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.<sup>59</sup> Additionally, publications used in connection with the sale of a dietary supplement to consumers when sold next to the products are considered labelling.<sup>60</sup> Nonetheless, these operations continue.

#### 4. *A Flexible FDA.*

The most important example of FDA flexibility has been in the area of regulation of homeopathy. Though clearly considered alternative medicine, homeopathy holds a special place in the regulatory framework because the chief sponsor of the 1938 FD&C Act was a homeopathic physician who included in the statutory definition of drug, homeopathic drugs.<sup>61</sup> FDA, however, regulates homeopathic drugs differently from other drugs in several ways: (1) homeopathic drug manufacturers are deferred from submitting NDAs, (2) homeopathic drugs are exempt from GMP requirements concerning expiration dating and from finished product testing for identity and strength, (3) homeopathic drugs in solid oral dosages must be imprinted with the manufacturer's name and indicate that the drug is homeopathic (this is different from the requirement that non-exempt conventional products identify the active ingredient and dosage strength as well as the manufacturer), (4) some homeopathic drugs are exempt from the 10% alcohol limit on conventional drugs.<sup>62</sup>

According to Edward Miracco, a consumer safety officer with FDA's Center for Drug Evaluation and Research, 'The reasoning behind [the difference] is that homeopathic products contain little or no active ingredients... From a toxicity, poison-control standpoint, [the active ingredient and strength] was deemed to be unnecessary... Overall, the disparate treatment has been primarily based on the uniqueness of homeopathic

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<sup>59</sup>21 U.S.C.A. §343(r)(6)(1997).

<sup>60</sup>21 U.S.C.A. §§343(r)(6) & 343-2 (1997).

<sup>61</sup>Isadora B. Stehlin, *Homeopathy: Real Medicine or Empty Promises?*, FDA CONSUMER, December 1996 [hereinafter *Homeopathy*]. See also 21 U.S.C.A. §321(g)(1)(1997).

<sup>62</sup>*Id.*

products, the lack of any real concern over their safety because they have little or no pharmacologically active ingredients, and because of agency resources and priorities.<sup>63</sup> This example of FDA flexibility provides hope for the Agency's willingness and capacity successfully to handle the challenges of alternative medicine.

*B. The Impact of FDA's Inconsistency*

With such varied responses to alternative medicine, different sectors of the population interpret FDA action quite differently. Some supporters of alternative medicine present a conspiracy theory:[G]overnment officials are in unholy alliance with the medical establishment and pharmaceutical industry, which would suffer enormous economic loss if people stayed healthy through good nutrition or could be cured with non-patentable drugs and other substances appearing commonly in nature.<sup>64</sup>

Pharmaceutical manufacturers, however, seem to take a different view of FDA on alternative medicine. One editorial in *Pharmaceutical Executive* ponders:

I have often questioned why so many alternative medicine practitioners get away with selling what seem to be drugs that haven't passed any FDA tests for safety and efficacy. So I've been heartened this past year by some examples of FDA intervention [such as FDA's raid of Dr. Stanislaw Burzynski], who for years has been peddling a 'miracle cure' for cancer... But FDA is both slow and timid... I understand FDA's caution in the matter. FDA is, after all, a political agency, and it faces potent opposition whenever it impedes the alternative medicine constituency. Conversely, FDA freely condemns pharmaceutical companies for allegedly promoting an FDA-approved medicine for purposes outside specific indications. But then, nobody has ever seen a public demonstration of support for a pharmaceutical company, and FDA Commissioner Dr. David Kessler, for one, never expects to.<sup>65</sup>

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<sup>63</sup> *Id.*

<sup>64</sup> *Questionable Tactics*, *supra*, note 61.

<sup>65</sup> *Roof & Remedies None of the Alternative Medicines in Today's Market Are New*, PHARMACEUTICAL EXECUTIVE, November 1, 1996.

The net result is that no one really knows where FDA stands on alternative medicine, but that's mostly because FDA itself is unsure. This uncertainty creates a real road block to the goal of making alternative medicine a safe and viable health care choice for Americans. People cannot make intelligent choices in health care without sufficient information. FDA's ambiguous-leaning-on-the-negative-side bias against alternative medicine contributes to a vicious cycle: As long as FDA appears poised to block alternative medicines, limited funding will go into its research. Without such research, many of these therapies will never achieve the scientific backing required to satisfy FDA. In testimony before the Senate concerning DSHEA, Robert McCaleb of the Herb Research Foundation described this dilemma as it relates to the herbal remedies industry:

The regulatory lockout of natural remedies has not only impeded the herbal products industry, denied valuable remedies to the elderly and minorities, but has crippled natural products research in our Universities and hospitals. The fields of Pharmacognosy (the study of drugs of natural origin) and other academic pursuits involving the study of medicinal plants have declined alarmingly in the U.S. American scientists, once at the forefront of this type of research, are lagging behind their European and Japanese counterparts, further reducing the likelihood of American discoveries of useful new medicines from plants. This is of concern to the academics themselves and should be to policy makers concerned with international competitiveness.<sup>66</sup>

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<sup>66</sup>McCaleb, *supra* note 17.

In addition to hampering research in the area of alternative medicines, this confusion also contributes to the safety problems. The more people think FDA is regulating, the less individual thought they will put into the safety of the products they use. If there is a significant disparity between the two, risk of people being injured will rise. For example, ephedrine, an amphetamine-like stimulant, has been marketed as a 'natural' substance to promote euphoria or increase energy,' under names like Cloud 9... , Ultimate Xphoria and Herbal Ecstasy.<sup>67</sup> Many people who used these products for the high ended up with strokes, heart attacks, or psychotic episodes. Some people died. Because herbal ephedrine is considered a dietary supplement, FDA did not regulate it. Whether public knowledge of that fact would have averted any harm in this example is unclear, but eliminating the guessing of what FDA is regulating could only be helpful.

A related problem is that such incidents trigger a blanket fear of herbal preparations, unnecessarily hampering development for legitimate uses. TCM has used herbals containing ephedrine, known as ma huang, for thousands of years to treat asthma and low blood pressure. These recent episodes serve only to generate thoughts that TCM is therefore dangerous and should not be used. As Dr. James S. Gordon, Chairman of the Program Advisory Council of the OAM, explained, Ma huang should be used intelligently [for certain indications], not indulged in, or promoted indiscriminately, for the 'high' it might give.<sup>68</sup> FDA needs to develop a sound policy toward alternative medicine that alerts customers to the risks of such products without destroying interest in using them for healthful purposes.

The guessing game of how FDA will react to a particular medicine, clinic or practitioner hinders the development of alternative medicine and prevents it from becoming a safe and reliable health care option.

## V. Regulatory Flexibility

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<sup>68</sup>James S. Gordon, *Unconventional Medicine Deserves Mainstream Attention*, THE WASHINGTON POST, October 6, 1996 at C4.

While many alternative medicines are conceptually different from conventional medicine, that reality does not make them wholly incompatible with the current regulatory structure. Neither giving up on alternative medicine because it does not fit into the conventional framework, nor creating an entirely new framework is necessary. FDA just needs to add flexibility to the current system through exemptions and adjusted standards. In deciding what alterations to make, FDA can turn to several sources for guidance.

Much of what we term *alternative medicine* in the United States is *conventional medicine* in other countries. Foreign models of regulation of certain therapies would be helpful in providing some guidance. For instance herbal medicine is highly developed in Germany. Although herbal product development is mostly motivated by demand, Germany's encouraging regulatory environment plays no small role.<sup>69</sup> In Germany approval of herbal drugs is based not only on study results, but also on clinical and pharmacological literature.<sup>70</sup> Germany's process has been described as requiring 'reasonable certainty' rather than 'absolute proof' of safety and efficacy which the FDA requires.<sup>71</sup> Under current FDA standards, the drug approval process costs are too high to provide any financial incentive to develop herbal drugs.<sup>72</sup> By studying the German system, FDA can work within its current framework to accommodate herbal and perhaps other alternative medicines. Additionally FDA could alter its regulations so that more foreign studies could be used to satisfy the standards for scientific evidence.

FDA should also consider how the regulatory exemptions permitted for homeopathic drugs might work for

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<sup>69</sup>Edgar R. Cataxinos, *Regulation of Herbal Medications in the United States: Germany Provides a Model for Reform*, 1995 UTAH L. REV. 561, 578 (1995).

<sup>70</sup>*Id.* at 579.

<sup>71</sup>*Id.*

<sup>72</sup>*Id.*

other types of alternative medicine. The main reason that FDA even bothered to find a way to fit homeopathic drugs within its regulatory scheme was probably because the statute made it inescapable. FDA needs to find similar solutions for other types of alternative medicine. As described in Section IV.A.4, FDA decided that as long as the safety concerns for homeopathic drugs were low, it would not worry as much about the lack of adequate efficacy evidence for homeopathic drugs. Why not apply the same reasoning to other bodies of medicine? The easiest ones to start with would be those that already have pharmacopoeias, such as TCM. As explained in Section III.A, the forms of alternative medicine with the greatest potential for Americans tend to be preventive in nature and safe because they are natural or used in very low dosages, as in homeopathy. According to Dr. David Eisenberg, director of the Center for Alternative Medicine Research at Beth Israel Hospital in Boston, 'I think that by and large the evidence is that many herbal products are safe.'<sup>73</sup> By providing certain exemptions, FDA could make a more flexible regulatory environment and increase the availability of drugs that are relatively safe, but whose efficacy has less scientific backing. FDA could also accept more foreign studies. As long as the drugs are clearly labelled as alternative, people will know that they are mostly safe, but they will have to do some individual experimentation of their own to determine just how useful the products will be to them. Collaboration with OAM would also be helpful in this area.

In adding flexibility to the regulatory climate, FDA should resist the temptation to keep as much control as possible. As the practice of alternative medicine becomes increasingly regulated by state law, the need for FDA to do more than ensure the safety of products diminishes.

By building additional flexibility into the current regulatory regime, FDA can sensibly accommodate alternative medicine without compromising the standards of conventional medicine.

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<sup>73</sup>Kolata, *supra* note 67.



## VI. Conclusion.

Alternative medicine has already established a role for itself in the health care of many Americans. FDA, however, has been slow to develop a meaningful and coherent regulatory response to this growing phenomenon. Reluctant to change its mind-set, FDA acts under the mistaken belief that the current regulatory scheme can accommodate any alternative medicine that will be useful to the public. Because of their conceptual and philosophical differences from conventional medicine, however, many alternative therapies simply cannot meet the demands of the current regulatory system. This reality does not imply that such medicines are not valuable. While it is true that many practices that are labelled *alternative* are nothing more than health fraud and often dangerous, there are also many medicines with great potential to improve how Americans think about and use medicine. A coherent policy toward alternative medicine and a more flexible regulatory scheme are required of FDA if Americans are to be given the freedom to choose different forms of health care safely and wisely.

### **FDA AND THE CHALLENGE OF ALTERNATIVE MEDICINE: REALISTIC ASSESSMENTS AND REGULATORY FLEXIBILITY**

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